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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/484,786	06/07/95	MACH	B MACH-2-CONT..

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EXAMINER

ARTHUR, L

ART UNIT  
1634

PAPER NUMBER

DATE MAILED: 01/22/99

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.	08/484,786	Applicant(s)	Mach et al.
Examiner	L. Arthur	Group Art Unit	1634

Responsive to communication(s) filed on Nov. 2, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 51-72 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 51-72 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This action is in response to the papers November 2, 1998. Currently, claims 51-72 are pending in this application. All of the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections which are not reiterated have been withdrawn as been obviated by the amendment of the claims. This action is FINAL.

**MAINTAINED REJECTION**

2. Claims 51-72 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record.

The response traverses the rejection on the following grounds. The response argues that the skilled artisan could use the instant specification to make the large number of sequences claimed using routine experimentation because the artisan would know that the useful DNA sequences are those that selectively hybridize and that determination of length is routine. The response alleges that once applicants identified the polymorphic and conserved region between DR-BA and DR-B-B, they also "made possible" sequences encoding these regions which specifically hybridize to the regions.

These arguments have been thoroughly reviewed but are deemed non-persuasive because they are allegations which are not supported by the level routine experimentation at the time of filing. As pointed out in the previous office action, in 1983 determination of hybridization

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conditions that allowed "specific hybridization" between nucleic acids which differed by only a few nucleotides was not routine. The methods at the time of the invention, such as Connor et al. Used short oligonucleotides (such as 19mers) under very high stringency hybridization conditions to differentiate alleles that differed by only a few nucleotides. The specification only discloses two specific sequences for comparison to detect mismatches for use in making such short oligonucleotides. Furthermore, the specification teaches that under high "criterium" hybridization conditions the inserts of DR-beta-A,B,C and D cross hybridize with one another such that the scope of "specific hybridization" is unclear. Further, the arguments are directed to embodiments to which the claims are not limited. The claims are very broadly drawn to any DNA sequence of any length that can hybridize to some unknown degree of specificity to the specific sequences of the specification. The claims are also drawn to sequences having portions containing any mismatch between these undiscovered hybridizing sequences. The locations, identities and sequences of these mismatch regions are unknown and completely unpredictable in light of the two specific sequences taught in the specification. The specification also does not provide guidance as to how to make sequences which "differ" from the specifically disclosed and the large number of "specifically hybridizing" sequences due to degeneracy of the genetic code. Therefore, this rejection is maintained.

The response traverses the rejection on the following grounds that the specification and the prior art taught how to make oligonucleotides which contained mismatches and how to use those oligonucleotides for HLA typing. All of the arguments and the cited references have been

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thoroughly reviewed but are deemed non-persuasive for the following reasons. The arguments are convincing that at the time of filing it would have been obvious to try to find oligonucleotides with the claimed characteristics. However, the specification and prior art do not provide enough specific guidance with regard to mismatches in the DR-B-A,B,C, D alleles and lack of cross reactivity to enable the skilled artisan to reasonably predict what the DNA sequences would be that would be useful for typing. The specification does not describe the structures of these oligonucleotides such that the skilled artisan would be able to reasonably predict what they would be without undue experimentation particularly in 1983. Therefore, for these reasons and the reasons of record, this rejection is maintained.

3. Claims 51-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,503,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent 5,503,976 are drawn to a specific embodiment, i.e. methods and kits using specific 19-mer oligonucleotides, which are encompassed in the more broadly drawn claims of the instant application.

This rejection is maintained pending the filing of a terminal disclaimer.

4. No claims are allowable.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Lisa B. Arthur*  
LISA B. ARTHUR  
PRIMARY EXAMINER  
GROUP 1800 (600)

January 19, 1999